Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0976641	06/18/2024
Name of Provider or Supplier	**Street Address, City, State**	
Centennial Medical Group	6250 Old Dobbin Lane Suite D, Columbia, MD	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on review of the proficiency testing (PT) procedure and instrument results and interview with the technical supervisor (TS), the laboratory failed to test PT samples the same number of times it tested patient specimens for the 2023 3rd PT event for the molecular Influenza A (Flu A) assay. Findings: 1. The "Proficiency Testing" procedure stated that "PT samples are run the same number of times as routine patient testing." 2. Instrument results were reviewed for Flu A PT sample 11 from the 2023 3rd event. 3. Flu A sample 11 was tested in triplicate. 4. During the survey on 06/18 /2024 at 12:30 PM, the TS confirmed that Flu A PT sample 11 was tested in triplicate and that patient samples were routinely tested once, not in triplicate.
D5016	ROUTINE CHEMISTRY CFR(s): 493.1210 If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1267, and 493.1281 through 493.1299.

	This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory failed to fully document the investigations and failed to address the potential impact on patient results when chemistry PT results were graded as unacceptable (see D5211 for findings); failed to have procedures to monitor, assess, and correct problems identified during the accessioning of patient specimens for chemistry (see D5391 for findings); failed to define criteria for temperature conditions for proper storage of reagents and specimens, accurate and reliable test system operation (see D5413 for findings); failed to ensure that the preventive maintenance information recorded on the chemistry records was complete (see D5429 cite I for findings); failed to have control procedures that monitored the accuracy and precision of the complete analytic process, detect and monitor quality control over time (see D5441 cites I, II, III, and IV for findings); failed to ensure that one or both Levels of the chemistry control reagent were tested each day of patient testing (see D5445 for findings); failed to establish or verify the criteria for acceptability of control materials providing quantitative results, statistical parameters (see D5469 for findings); failed to take corrective action (see D5779 for findings); and failed to document all corrective actions taken, including actions taken when results of control materials failed to meet the laboratory's established criteria for acceptability and take the corrective action necessary to ensure the reporting of accurate and reliable patient test results (see D5783 for findings). The cumulative effect of these systemic problems resulted in the laboratory's inability to ensure the accuracy and reliability of patient test results.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of the proficiency testing (PT) procedure and PT records and interview with the assistant manager (AM) and technical supervisor (TS), the laboratory failed to fully document the investigations and failed to address the potential impact on patient results when PT results were graded as unacceptable. Findings: 1. The laboratory was enrolled in PT with the American Proficiency Institute (API) in modules for Chemistry - Core, Chemistry - Miscellaneous, Hematology/Coagulation, and Microbiology. 2. The "Proficiency Testing" procedure stated that "Any analytes found to be unsatisfactory or if ungraded an investigation should occur to include documentation of findings. Proficiency Exception Form," "When an unsatisfactory result is received, a full investigation will be conducted to determine the cause (Root Cause Analyze)," and "An exception form will be filled out for analytes on that survey that does not meet full approval from API." 3. For the Chemistry - Core 2023 3rd event: a. The laboratory received a score of 60% for Bilirubin, Total. The performance review stated "After investigation it was determined that the reagent lot was unacceptable after QC and calibration. Old lot was removed from testing and a new lot placed in production with freshly made calibrators which passed with no flags." b. There was no additional documentation detailing how it was determined that the "lot was unacceptable," how long that "unacceptable" lot was on the analyzer, and whether patient results were affected by the "unacceptable" reagent lot for Bilirubin, Total. 4. For the Chemistry - Core 2024 1st event: a. The laboratory received a score of 80% for Bilirubin, Direct; Cholesterol, Total; and

sodium. b. The laboratory received a score of 60% for Chloride and LDL (low-density lipoprotein). c. The performance review stated "LDL samples CH-02 and CH-03 were graded as unacceptable. After investigation for the root cause analysis determination was the instrument probe went bad. New probe was installed and linearity was performed which had an R^2 of 0.98." d. There was no additional documentation detailing how it was determined that the instrument probe "went bad," how long the instrument probe was "bad" for, and whether patient results were also affected by the "bad" instrument probe. e. There was no documented investigation into the failed Chloride results. f. The laboratory also had unacceptable results for direct bilirubin, total cholesterol, and sodium that were not addressed. 5. For the Chemistry - Miscellaneous 2023 1st event: a. During the onsite survey on 03/07/2024, the AM confirmed that toxicology patient results were reported beginning on 04/14/2023 and ending on 07/20/2023. b. The laboratory received a score of 67% for specific gravity (UAD quant) and UDS Alcohol (quant). c. The performance review signed by the TS and laboratory director on 05/23/2023 stated "Specific gravity and alcohol were graded unacceptable for sample UAD-03. After investigation it was identified as environmental inconsistencies the 2 reagents are hypersensitive to temperature. Air handler was installed to alleviate temperature issues. No patient samples were affected, tox program was discontinued at this time." d. There was no additional documentation detailing how it was determined that those 2 reagents were hypersensitive to temperature and whether the temperature issues could have occurred when patient testing began on 04/14/2023. The review stated that the tox program was discontinued at that time, but according to the AM, patient results were reported up to 07/20/2023. There was no documentation stating whether patient results could have been affected by the 2 reagents that were hypersensitive to temperature. 6. For the Hematology 2023 1st event: a. The laboratory received a score of 80% for white cell count. b. The performance review stated that "After investigation to the cause it was determined that the basophil loop was encrusted with cellular debris. Per manufacturer recommendation we bleached the line for the loop, soaked the basophil loop and performed a shear valve clean ahead of schedule." c. There was no additional documentation detailing how it was determined that the basophil loop was encrusted with cellular debris, how long the loop was encrusted with debris, and whether patient results could have been affected by the basophil loop being encrusted by cellular debris. 7. For the Hematology 2023 3rd event: a. The laboratory received a score of 80% for monocytes. b. The performance review stated "After investigation to the cause was determined that the manufacturer's cleaning solution was deemed insufficient by manufacturer. Diatron sent a new recommended cleaning solution." c. There was no additional documentation detailing how it was determined that the cleaning solution was insufficient and whether the insufficient cleaning solution might have affected patient results. 8. For the Microbiology 2022 3rd event: a. The laboratory received a score of 50% for Proteus mirabilis. b. The performance review stated that "Upon investigation it was determined the error was a clerical error." c. There was no additional documentation detailing what kind of clerical error led to the unacceptable results or what corrective actions were taken to ensure that the clerical error did not recur. 9. For the Microbiology 2023 2nd event: a. The laboratory received a score of 80% for Neisseria gonorrhoeae, Legionella pneumophila, human metapneumovirus, human rhinovirus/enterovirus, influenza (Flu) A, Flu A H3, respiratory syncytial virus (RSV), rhinovirus, SARS-CoV-2, Enterococcus sp., Enterococcus faecalis, Serratia marcescens, Candida albicans, and the antibiotic resistance gene sul. b. The performance review stated that "N. gonorrhoeae was graded as unacceptable, the issue was a clerical error. The PCR run file shows a positive Ct result for N. gonorrhoeae." c. There was no documented investigation into why the other gene targets had unacceptable results. 10. For the Microbiology 2023

	3rd event: a. The laboratory received a score of 80% for Flu A, Aerococcus urinae, and the antibiotic resistance genes sul1 and sul2. b. The laboratory received a score of 60% for Flu B and Staphylococcus aureus. c. The laboratory received a score of 40% for RSV. d. The laboratory received a score of 20% for Acinetobacter baumannii. e. The performance review stated that "After exploring possible causes for result discrepancies, ran samples with different reagent lots, results did not change. Ct values reflected positive targets." f. There were no additional investigations into the root cause of the unacceptable PT results and whether patient results were affected. 11. A "Proficiency Exception Form" was not filled out for any of the unacceptable PT results as stated in the PT procedure. 12. During the survey on 03/07/2024 at 2:35 PM, the TS confirmed that the investigations into the root cause of the PT failures were incomplete and didn't address potential effects to patient results.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on review of the proficiency testing (PT) procedure and PT records and interview with the laboratory manager (LM), the laboratory failed to self-evaluate PT results that were not graded by the PT program. Findings: 1. The "Proficiency Testing" procedure stated that "Any analytes found to be unsatisfactory or if ungraded an investigation should occur to include documentation of findings." 2. The following events included results that were "Not Graded" by the PT provider. a. 2022 Microbiology 3rd Event: antibiotic resistance genes AmpC, CTX-M, dfrA, IMP, KPC, mecA, OXA, qnr, SHV, sul, TEM, vanA/B, and VIM b. 2023 Chemistry - Miscellaneous 1st Event: Specific Gravity, UAD interpretation c. 2023 Hematology /Coagulation 2nd Event: Monocytes d. 2023 Microbiology 2nd Event: Citrobacter sp., Candida sp., dfrA, KPC, sul, Tet M, and vanA/B e. 2023 Hematology/Coagulation 3rd event: Monocytes f. 2023 Microbiology 3rd Event: Aerococcus urinae, sul1, and sul2 g. 2024 Chemistry - Core 1st Event: Bilirubin, Total h. 2024 Hematology/Coagulation 1st Event: Monocytes i. 2024 Microbiology 1st Event: CTX-M Group 1, dfrA, KPC, mecA, NDM, OXA, qnrA, qnrS, sul1, sul2, vanA, and vanB 3. During the exit interview on 06/18/2024 at 3:00 PM, the LM confirmed that there was no documented self-evaluation of ungraded PT results.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of the proficiency testing (PT) procedure, the test menu, PT records, and the PT provider's catalogue and interview with the laboratory manager (LM), the laboratory failed to verify the accuracy of all gene targets included in the polymerase chain reaction (PCR) panel testing at least twice annually. Findings: 1. The laboratory was enrolled in PT with American Proficiency Institute (API). 2. The "Proficiency

	Testing" procedure stated "The laboratory will enroll in the API proficiency testing yearly for all testing that is performed in the lab. If there is not an API survey for all analytes, blind studies made up and will be given to the analysts for testing twice per year." 3. The laboratory's respiratory PCR panel included targets for respiratory syncytial virus (RSV) A and B. The laboratory was enrolled in API for RSV which did not differentiate between RSV A and B. 4. The laboratory's sexually transmitted infection PCR panel included targets for human immunodeficiency virus (HIV)-1, HIV-2, hepatitis B, and hepatitis C. None of the API performance evaluations included results for HIV-1, HIV-2, hepatitis B, and hepatitis C. 5. The laboratory's urinary tract infection PCR panel included targets for Candida auris and the antibiotic resistance genes blaFOX, blaVEB, dfrA1, and dfrA5. The laboratory was enrolled in the API molecular biology - urine PT program. The API catalogue did not list Candida auris, blaFOX, blaVEB, dfrA1, or dfrA5 as gene targets included in the molecular biology - urine PT program. The antibiotic resistance gene target dfr was available, but this did not differentiate between dfrA1 and dfrA5. 6. During the exit interview on 06/18/2024 at 3:00 PM, the LM confirmed that the laboratory did not perform any blind studies or alternate PT to verify the accuracy of the gene targets for RSV A, RSV B, HIV-1, HIV-2, hepatitis B, hepatitis C, Candida auris, blaFOX, blaVEB, dfrA1, and dfrA5 at least twice annually.
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory failed to establish written policies and procedures for specimen acceptability and rejection (see D5311 for findings); and failed to establish procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems (see D5391 for findings). The cumulative effect of these systemic problems resulted in the laboratory's inability to ensure the accuracy and reliability of patient test results.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: I. Based on review of the written procedure for specimen accessioning and interview, the laboratory did not have a procedure for accessioning patient specimens other than

	those collected for polymerase chain reaction (molecular) testing. Findings: 1. The laboratory's written procedures for hematology and chemistry did not include instructions for specimen rejection. 2. During the exit interview on June 18, 2024 at 2: 30 PM, the technical supervisor confirmed that the specimens collected for chemistry were not included in the accessioning procedures. 38127 II. Based on procedure and instrument operator's manual review and interview with the laboratory manager (LM), the laboratory failed to establish and follow written policies and procedures for hematology specimen acceptability and rejection to ensure accurate and reliable results. Findings: 1. During a tour of the laboratory on 05/29/2024 at 10:20 AM the LM stated that complete blood count (CBC) specimens must be run within eight hours of collection. 2. The laboratory's procedure manual, "Abacus Diatron 5 Standard Operating Procedure" states under "Specimen Requirements" that the specimens should be run, "between 30 minutes and 24 hours of collection"; and 3. The "Abacus 5 Innovative Solutions in Hematology Operator's Manual" states under section, "8.1.4 Sample Collection and Handling" that "a minimum of 30 minutes should elapse between taking the blood sample and running it on the 'Abacus 5' for analysis to ensure that the interaction of blood and anticoagulant has fully stabilized" and that the lab should "analyze blood samples within 7 hours of collection." 4. A review of the specimen collection and results reporting dates and times for 936 CBC specimens from January through June 2024 showed that 29 out of 936 CBCs were tested and resulted less than 30 minutes from the time of collection; and 5. 108 out of 936 CBC specimens were tested and resulted more than seven hours after collection. 6. During the exit interview on 06/18/2024 at 2:30 PM, the LM confirmed that the stability limits stated in the laboratory's written procedure manual for CBCs were incorrect and did not reflect the manufacturer's instructions, and that the laboratory was not monitoring collection and specimen run times to ensure that hematology specimens were run within the manufacturer's stated stability requirements.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on review of the laboratory's written procedure for specimen accessioning and interview, the laboratory did not have procedures to identify and track problems during the accessioning of patient specimens for chemistry and hematology testing. Findings: 1. The laboratory's written procedures for hematology and chemistry did not include instructions to maintain a list of accessioning problems for the lab to track to determine if corrective actions previously taken were effective. 2. During the exit interview on June 18, 2024 at 2:30 PM, the technical supervisor confirmed that the laboratory did not establish indicators for problems identified during specimen accessioning.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that

	provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on interview and record review, the laboratory failed to have written instructions for each step of hematology and molecular testing (see D5403 for findings); failed to maintain a copy of each procedure with the dates of initial use and discontinuance (see D5409 for findings); failed to define criteria for temperature conditions for proper storage of reagents and specimens, accurate and reliable test system operation (see D5413 for findings); failed to ensure that reagents were not used past expiration (see D5417 for findings); failed to perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer (see D5429 for findings); failed to have control procedures that monitor the accuracy and precision of the complete analytic process, to detect immediate errors that occur due to test system failure, monitor over time the accuracy and precision of test performance (see D5441 for findings); failed to use a quality control reagent that provided quantitative results for the amylase test (see D5445 for findings); failed to establish or verify the criteria for acceptability of control materials providing quantitative results, statistical parameters (see D5469 cite II for findings); failed to check each lot number and shipment of commercially prepared molecular test reagents for positive and negative reactivity (see D5471 for findings); failed to have a system that twice a year evaluated and defined the relationship between test results using the different methodologies, instruments, or testing sites in use (see D5775 for findings); failed to take and document corrective action when control results did not meet acceptable criteria to show accuracy and repeatability within the test system (see D5779 for findings); and failed to document all corrective actions taken, including actions taken when results of control materials failed to meet the laboratory's established criteria for acceptability and take the corrective action necessary to ensure the reporting of accurate and reliable patient test results (see D5783 for findings). The cumulative effect of these systemic problems resulted in the laboratory's inability to ensure the accuracy and reliability of patient test results.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values.

(14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:
I. Based on procedure and instrument operator's manual review and interview with the laboratory manager (LM), the laboratory failed to provide the testing personnel with written preanalytical, analytical, and post analytical policies and procedures for testing with the Diatron Abacus 5 hematology analyzer. Findings: 1. A review of the procedure, "Abacus Diatron 5 Standard Operating Procedure" showed that there were no written procedures for step-by-step performance of the procedure, including test calculations and interpretation of results; calibration and calibration verification procedures; corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability; limitations in the test methodology, including interfering substances; reference intervals (normal values); imminently life-threatening test results, or panic or alert values; the laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values; or a description of the course of action to take if a test system becomes inoperable. 2. The "Abacus Diatron 5 Standard Operating Procedure" states, "for calibration, analyzer maintenance and troubleshooting, see the following link" and provides a web address to access the instrument user manual online. 3. A review of the "Abacus 5 Innovative Solutions in Hematology Operator's Manual" showed that it was not written specifically for the laboratory and was a generic user manual. The user manual was not approved by the laboratory director. 4. During the exit interview on 06/18 /2024 at 2:30 PM, the LM confirmed that the laboratory did not provide approved written preanalytical, analytical, and post analytical policies and procedures for testing with the Diatron Abacus 5 hematology analyzer. 38127 II. Based on review of the validation procedures and interview with the technical supervisor (TS), the laboratory did not have a procedure for the optimization of cycle threshold (Ct) cutoff values for the molecular urinary tract infection (UTI) and Coronavirus Disease 2019 (COVID-19)/Influenza A and B (Flu A&B)/Respiratory Syncytial Virus A and B (RSV A&B) assays. Findings: 1. The validation reports for the UTI and COVID-19/Flu A&B/RSV A&B assays were reviewed. 2. The "Dynamic Range" section of the validation reports listed the Ct cutoff values used for each assay and for the UTI assay stated, "The CT cut-off should be re-assessed annually, or as needed" and for the COVID-19/Flu A&B /RSV A&B assay stated, "The CT cut-off should be re-assessed bi-annually, or as needed." 3. At 1:15 PM on 05/29/2024, the TS stated that the testing personnel (TP) documented the Ct values for positive patient results on a graph and the TS evaluated the Ct values to optimize the cut-off ranges. 4. During the survey on 05/29/2024 at 3: 15 PM, the TS confirmed that the Ct values for the molecular assays were routinely reviewed, but there was no procedure that included instructions for the TP to document positive patient Ct values on a separate graph and for the TS to evaluate the documented Ct values to optimize the Ct cut-off ranges. III. Based on review of the procedure, review of the manufacturer's instructions for use (IFU), and interview with the technical supervisor (TS), the laboratory's procedure for performing the COVID-19 /Flu A&B/RSV A&B assay did not include instructions for how to prepare and dispense the RSV A&B reagents onto the plate, for when to add the MS2 internal control to patient specimens, and for prepping and aliquoting the positive control. Findings: 1. The laboratory's COVID-19/Flu A&B/RSV A&B assay used the TaqPath COVID-19, FluA, FluB Combo Kit from ThermoFisher Scientific and then added custom RSV A and RSV B single tube assays to the testing panel so that each patient specimen was tested with three different master mixes. 2. The procedure listed the reagent volumes required to prepare the reaction mix for the TaqPath COVID-19,

	FluA, and FluB reagent mix, but did not include the reagent volumes required to prepare the reaction mixes for RSV A and RSV B. 3. The procedure did not include a plate map or instructions for how to orient patient specimens for the RSV A and RSV B assays on the testing plate with the COVID-19/Flu A&B assay. 4. The TaqPath COVID-19, FluA, FluB Combo Kit manufacturer's IFU included instructions for adding the MS2 phage internal control to patient specimens prior to extraction. The laboratory's procedure did not state when the MS2 phage internal control should be added to patient specimens. 5. The manufacturer's IFU also included instructions for diluting the COVID-19, FluA, FluB positive control to a working stock using the dilution buffer. The laboratory's procedure did not include instructions for preparing and aliquoting the working stock of positive control for the COVID-19/Flu A&B assay. 6. During the survey on 05/29/2024 at 2:00 PM, the TS confirmed that the written and approved testing procedure did not include instructions for how to prepare and dispense the RSV A&B reagents, when to add the MS2 internal control to patient specimens, and how to prepare and aliquot the positive control. 43123
D5409	PROCEDURE MANUAL CFR(s): 493.1251(e) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2). This STANDARD is not met as evidenced by: Based on review of the written procedure manual and interview with the technical supervisor (TS), the laboratory failed to label procedures no longer in use with the date they were discontinued. Findings: 1. The procedure manual that was reviewed had an unlabeled section at the end with duplicate procedures for the Wipe Test, Quality Control Covid and Flu, and Proficiency Testing. According to the TS these procedures had been discontinued and the updated procedures were in the appropriate sections. 2. The procedures in the unlabeled section failed to have the date of discontinuance documented on each procedure. 3. During the survey on 03/07/2024 at 2:30 PM, the TS confirmed that the procedures had not been labeled as discontinued.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of temperature records and interview, the acceptability of the laboratory room temperature was not defined in a manner to ensure identification of unacceptable temperature readings. Findings: 1. The laboratory's acceptable range for the room temperature is 68 degrees Fahrenheit (DF) to 75 (DF) (+/- 5 DF) as documented on the temperature record. The record did not explain if the +/- 5 DF was to be applied to the upper and lower limits already given or if there was a median

	value to apply the 5 DF range. 2. The laboratory's written procedure (Temperature and Humidity Checks) did not identify the acceptable range for the room temperature. 3. The temperature recorded on the log/humidity report for tempstick 6029488 for 1/20 /2024 was 61.5 DF, the temperature did not meet the laboratory's criteria for acceptability, and there was no comment for corrective action documented on the report. 4. During interview on 6/18/24 at 2:30 PM, the technical supervisor confirmed that the additional application of the +/- 5 DF was not defined.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: I. Based on hematology reagent log record review, surveyor observation, and interview with the laboratory manager (LM), the laboratory failed to ensure that reagents used for hematology testing are not used when they have exceeded their expiration date. Findings: 1. During a tour of the laboratory on 05/30/2024 at 2:30 PM, it was observed that the Abacus 5 hematology analyzer did not store the lot numbers and expiration dates of reagents used for testing. The instrument records the volume of the newly placed reagent as "100%" but does not document the lot number and expiration date, nor the time and date that the reagent was loaded onto the instrument. 2. Record review showed that the laboratory documented lot numbers and expiration dates of reagents on the manifest received with each order of reagents. The laboratory entered some of this information onto a spreadsheet, however neither record documented the date and time that the reagent was loaded onto the instrument and used for patient testing. 3. During an interview on 05/30/2024 at 2:30 PM, the LM confirmed that the laboratory did not have documentation of when hematology reagents were put into use for patient testing, and did not ensure that reagents were not used past their expiration date. 43123 II. Based on review of the procedure, review of batch worksheets, and interview with the technical supervisor (TS), the laboratory failed to document the lot number and expiration date for extraction reagents used for the molecular sexually transmitted infections (STI) panel. Findings: 1. The laboratory's molecular STI panel testing included a procedure for extracting DNA of patient specimens prior to amplification. 2. The laboratory documented the lot numbers and expiration dates for the reagents used for amplification on a batch worksheet, but did not document the lot numbers and expiration dates of the reagents used for extraction. 3. During the survey on 05/30/2024 at 3:30 PM, the TS confirmed that the lot numbers and expiration dates for the extraction reagents used for patient testing on the molecular STI panel assay were not documented on the batch worksheets or anywhere else.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii)

	Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the validation records for the hematology analyzer and interview with the technical supervisor (TS), the laboratory failed to ensure that one set of validation documents were approved and there was a written procedure with instructions for how to accurately perform the validation and evaluate the results. Findings: 1. The laboratory moved the hematology analyzer to a new location on April 2, 2024, and performed the re-validation of the hematology analyzer. The re-validation binder included 4 sets of validation documents that were all approved by the TS. 2. When interviewed the TS stated that the re-validation was performed by the support staff from the manufacturer of the hematology analyzer and that there was no written procedure with instructions on how the re-validation was performed. 3. During the survey on 06/18/2024 at 3:00 PM, the TS confirmed that there should have been one set of re-validation records and that there was no written and approved procedure with instructions on how the re-validation was performed.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: I. Based on review of maintenance records, the laboratory did not ensure that the information recorded on the records was complete. Findings: 1. The temperature stick calibration report for the month of March 2024 was documented as being performed on 1/30/2024. 2. The chemistry Maintenance Monthly report for December 2023 did not identify the testing person who performed the maintenance duties for 11 of 70 activities performed throughout the month, instead of initials the testing person performing maintenance recorded a check mark. 3. The chemistry maintenance monthly report for April 2024 was missing documentation to show maintenance was performed from 4/1/2024 to 4/16/2024, except for 4/11/2024 that was only missing documentation for probe cleaning and ISE cup cleaning. There was no record during the month to show testing was suspended for the beginning of April 2024, as this would have assisted the laboratory manager's monthly review of laboratory test records. 38127 II. Based on hematology instrument record review and interview with the testing person (TP), the laboratory did not ensure that routine maintenance was performed and documented on the Diatron Abacus 5 hematology analyzer as recommended by the manufacturer. Findings: 1. The "Abacus 5 Innovative Solutions in Hematology Operator's Manual" stated under section, "17 Maintenance," "17.6 Cleaning the Shear Valve" that "it is recommended that the operator clean the shear valve after every 1200 samples"; and 2. Section "17.8.1 Daily Cleaning" stated, "The Shutdown function at the end of the daily routine will request that a sample vial with 2-3 ml of DiatroHypocleaner CC reagent with no cap be placed into the sample rotor. The software shutdown function will clean the tubing in the measurement system." 3. Review of hematology instrument records from 2023 and 2024 showed that there was no documentation that instrument maintenance had been performed. 4. During an interview on 05/29/2024 at 3:30 PM, TP #1 stated that there was no written

	documentation that preventative maintenance had been performed on the Abacus 5 hematology analyzer.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: I. Based on record review and communicated by email from the laboratory, the laboratory did not monitor the accuracy and precision of the Level B (high range control) for patient amylase testing. Findings: 1. The Level B quality control reagent (to check the accuracy and precision of high test results) did not provide numeric test results for amylase. Since the amylase test is a quantitative test, and the Level B control could not provide quantitative test results on the test system in use, the control could not detect immediate errors or monitor accuracy and precision of testing over time. 2. The analyzer reported the result of RH or range high for the results of the Level B amylase test, and since RH is not a numeric result, statistical analysis of the control test results could not be performed for daily accuracy, and Levey-Jennings charts could not be generated for long term review for shifts or trends in quality control results. This was confirmed during an interview with the technical supervisor on May 30, 2024, at 3:00 PM. 3. The amylase Level B control was reported by the analyzer as RH for all months reviewed for August 2023, September 2023, October 2023, November 2023, December 2023, and May 2024. 4. Patient samples for amylase were tested on August 4, 17, and 22, 2023, September 8 and 21 of 2023, October 16, 20, and 24, 2023, November 1, 6, and 28, 2023 and December 5 and 13, 2023 as stated in an email from the laboratory manager dated July 25, 2024. II. Based on record review, the chemistry laboratory did not ensure quality control testing was performed each day of patient testing to detect immediate failures in testing. Findings: 1. The chemistry quality control Levey-Jennings charts and the laboratory manager's email response dated 7/25/2024 to the surveyor's inquiry into dates of patient testing, showed the laboratory failed to ensure quality control testing was performed on the following days for the analytes listed below. a) On September 1, 4, 5, 6, 7, 11, and 12, 2023, patient testing was performed for alkaline phosphatase, alanine aminotransferse, albumin, blood urea nitrogen, chloride, carbon dioxide, creatinine, glucose, potassium, sodium, total bilirubin, total protein, high density lipoprotein, low density lipoprotein, and triglycerides when the Level B quality control reagent was not tested to check the accuracy of the test system. b) On September 1, 4, 5, 6, 7, and 8, 2023, patient testing was performed for aspartate aminotransferase and calcium when the Level B quality control reagent was not tested to check the accuracy of the test system. c) On September 1, 4, 5, 6, 7, 8, and 11, 2023, patient testing was performed for cholesterol, when the Level B quality control reagent was not tested to check the accuracy of the test system. d) On October 11, 12, 13, and 16, 2023, patient testing was performed for

	sodium when the Level B quality control reagent was not tested to check the accuracy of the test system. e) On November 6, 17, and 28, 2023, patient testing was performed for calcium when both Level A and B quality control reagents were not tested to check accuracy of the test system. f) On November 17, 2023, patient testing was performed for creatinine when the Level B quality control reagent was not tested to check accuracy of the test system. g) On November 17 and 28, 2023, patient testing was performed for AST, ALT, alkaline phosphatase, glucose, blood urea nitrogen, magnesium, total protein, bilirubin, albumin, and carbon dioxide when both Level A and B quality control reagents were not tested to check accuracy of the test system. III. Based on record review, the chemistry laboratory did not ensure quality control test results met the laboratrory's criteria of acceptability before testing patient samples. Findings: 1. On December 11, 2023, the result of the low density lipoprotein (LDL) Level A quality control reagent initially failed to meet the laboratory's criteria of acceptability and was retested. The retest result was 44 mg/dl (acceptable limits were 34-44 mg/dl) and this control result just met the value for the higher end of this control. The Level B quality control reagent was tested three times with results of 130 mg/dl, 124 mg/dl, and finally 124 mg/dl (acceptable limits were 100 - 120 mg/dl). This control was unacceptable for all three tests with all three results on the high side of the allowable range. On December 11, 2023, despite the quality control failure, patient samples were tested and reported for LDL, as communicated in the laboratory managers email dated July 25, 2025. IV. Based on record review and interview, the chemistry laboratory did not conduct and document quality control reviews as stated in the written procedure. Findings: 1. The written quality control procedure (Lab-25) states that review of Levey-Jennings charts are performed weekly and documented on the review form, instead the Levey-Jennings charts were reviewed monthly and the review form was not used. 2. The Levey-Jennings charts used to conduct quality control reviews were not maintained and the Levey-Jennings chart for the level B control for all chemistry analytes for August 2023 was corrupted and was not even available for reprint. 3. This was confirmed with the technical supervisor during an interview at 12:00 PM on May 30, 2024. V. Based on procedure manual and quality control (QC) record review and interview with the testing person (TP), the laboratory did not perform and document the weekly review of hematology QC. Findings: 1. The procedure, "Quality Control: Covid, Flu, STI, UTM, Clinical Chemistry and Hematology" states that "for test that result numeric value, electronic LJ [Levey-Jennings] plots must be reviewed weekly and documented on the review form" and that "any trends/shifts must be documented on the QA form in the corrective action section of the log." 2. Hematology QC record review showed that there were no "review forms" available at the time of the survey. 3. During an interview on 05/30 /2024 at 2:45 PM, the TP stated that no one is reviewing the LJ plots to identify shifts and trends in hematology QC.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on review of Levey-Jennings (L-J) charts and emailed responses from the laboratory, the laboratory did not ensure that one or both Levels of the chemistry control reagent were tested each day of patient testing as required by the manufacturer. See D5441 Cite I and II for findings.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: I. Based on record review, the laboratory did not perform parallel quality control checks to verify new lots of chemistry quality control reagent prior to being placed in use. Findings: 1. The written quality control procedure states that a parallel check between the lot number of chemistry quality control reagent taken out of use be checked with the new lot of quality control reagent that will be placed in use, to verify that the results of the quality control reagents to be placed in use are recovered as required by the manufacturer to detect problems with test performance. 2. The parallel checks between the old and new lot of chemistry quality control reagent were not performed. Records for the chemistry quality control checks were not available for review. II. Based on review of quality control records, the laboratory did not ensure that the Level B quality control reagent met the laboratory's requirements to quantitatively monitor accuracy and precision of patient amylase testing. See D5441 Cite I for findings.
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the procedure, the manufacturer's User Guide, and quality control

	(QC) data and interview with the technical supervisor (TS), the laboratory failed to verify positive and negative reactivity for each new lot number and shipment of pre-filled polymerase chain reaction (PCR) plates used for the molecular Urinary Tract Infection (UTI) panel assay. Findings: 1. The laboratory used PCR plates that were received pre-filled from the manufacturer for the molecular UTI panel assay. 2. The UTI panel assay was a laboratory developed test that identified 20 pathogens and 15 antibiotic resistance genes for a total of 35 targets. 3. The laboratory tested a positive QC with each batch of patient specimens that included 4 of the 35 targets. 4. There was no documentation that the positive and negative reactivity for the remaining 31 targets was performed for each lot of UTI PCR plates. 5. There was no documentation from the manufacturer stating what type of QC was performed for each lot number of UTI PCR plates prior to shipment to the laboratory. 6. During the survey on 06/18 /2024 at 9:20 AM, the TS confirmed that the manufacturer could not provide documentation of the QC performed on each lot number of UTI PCR plates prior to shipment and that the laboratory did not verify the positive and negative reactivity for each new lot number and shipment of plates that was received.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on review of the procedures and interview with the technical supervisor (TS), the laboratory failed to perform a comparison of test results for the molecular assays that were performed on two different polymerase chain reaction (PCR) instruments. Findings: 1. The laboratory's procedures stated that the molecular sexually transmitted infections (STI) and Coronavirus Disease 2019 (COVID-19)/Influenza A and B (Flu A & B)/Respiratory Syncytial Virus A and B (RSV A & B) assays could be run on either the QuantStudio 5 (QS5) or QuantStudio 12K Flex (QS12K) PCR instruments. 2. During the survey on 06/18/2024 at 12:28 PM, the TS confirmed that a comparison of results for the molecular STI and COVID-19/Flu A & B/RSV A & B assays from the QS5 and QS12K PCR instruments was not performed at least twice a year.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by: I. Based on record review and interview, the laboratory did not maintain a corrective action log for the testing person to document quality control failures, corrective actions, and outcomes for chemistry testing performed on patient specimens. Findings: 1. The laboratory did not maintain a chemistry corrective action log to document corrective actions when quality control results did not meet the laboratory's

criteria for acceptability. The laboratory did not have a reliable procedure to document corrective actions that include repeat testing of quality control reagent when the original result did not meet the laboratory's criteria for acceptability or other troubleshooting activities such as maintenance, calibration, or suspension of testing pending resolution. 2. The technical supervisor did not have procedures to monitor corrective action logs to ensure staff took corrective actions, and to notify the laboratory director of testing problems in chemistry. This was confirmed with the technical supervisor during the exit interview conducted the afternoon of June 18, 2024. II. Based on review of quality control records, the chemistry laboratory did not take corrective actions when the level B amylase control failed to provide numeric statistically reviewable results. Findings: 1. The amylase test is a quantitative test and the level B control reported the results as RH or range high, even though the mean value of the control was 252 u/l and within the analytic range of 16 u/l to 481 u/l for the analyzer. 2. In an email dated 7/8/2024, the technical supervisor stated that staff were trained to accept RH as an acceptable control result even though it failed to provide a statistically reviewable result. 3. In an email from the laboratory manager dated 7/25/2024, it was confirmed that patient testing for amylase was performed on August 4, 17, and 22, 2023, September 8 and 21, 2023, October 16, 20, and 24, 2023, November 1, 6, and 28, 2023, and December 5 and 13, 2023 while the Level B control failed to meet the laboratory's criteria for acceptability. 4. See D5441 Cite I for findings III. Based on record review, the laboratory did not take corrective action when chemistry quality control testing for low density lipoprotein (LDL) did not meet the laboratory's criteria for acceptability and reported patient test results. Findings: 1. The laboratory tested and reported low density lipoprotein results when the quality control results did not meet the laboratory's criteria for acceptability. See D5441, Cite III and D5211 cite #4 for additional findings. 2. The laboratory had a persistent shift in LDL quality control test results leading up to proficiency test failure for LDL when the laboratory obtained a 60% score for LDL on the Chemistry-Core 2024 first event. The cause of the problem was identified as a bad probe by the laboratory. The corrective actions failed to include a review of quality control test results for long term failures in quality control, a look back to the last successful proficiency test result for LDL, a determination of patient risk during the shift in the mean quality control test results, and retraining for the laboratory manager to identify and report quality control shifts or trends, as indicated. See IV below for additional findings. IV. Based on review of Levey-Jennings charts, the chemistry laboratory did not take corrective actions when the low density lipoprotein (LDL) quality control test results showed a shift in the mean. Findings: 1. The laboratory did not take corrective action when the low density lipoprotein (LDL) control reagent showed a persistent shift in quality control results. The assayed mean of the Level A control was 39 mg/dl with an acceptable 2 standard deviation (SD) range of 34 to 44 mg/dl. The assayed mean of the Level B control was 110 mg/dl with an acceptable 2 SD range of 100 to 120 mg /dl. 2. In September 2023, the Levey-Jennings chart showed the calculated mean for the level A control at 42 mg/dl (at 1 SD), and the calculated mean for the level B control at 119 mg/dl (approaching 2 SD). 3. In October 2023, the Levey-Jennings chart showed the calculated mean for the Level A control at 41 mg/dl (at 1 SD), and the calculated mean for the Level B control at 115 mg/dl (at 1 SD). 4. In November 2023, the Levey-Jennings chart showed the calculated mean for Level A at slightly below 1 SD, and the calculated mean for the Level B control was 119 mg/dl (close to 2 SD). 5. In December 2023, the Levey-Jennings chart showed the calculated mean for Level A at 2 SD, and the calculated mean for the Level B control was 120 mg/dl (2 SD). 6. In January 2024, the Levey-Jennings chart showed the calculated mean for Level A at 44 mg/dl, (2SD) and the calculated mean for the Level B control at was 118 mg/dl (close to 2 SD).

D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory did not take corrective actions when quality control test results did not meet the laboratory's criteria for acceptability, including when the laboratory did not perform quality control testing, failed to perform weekly reviews of Levey-Jennings charts, failed to identify shifts, and failed to ensure that controls used to monitor quantitative testing provided numeric results for statistical analysis. See D5441 for findings.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on record review, the laboratory did not provide documentation of chemistry testing for patient samples identified on a spreadsheet. The spreadsheet [CBC'S Report (January - June 2024)- Copy] was sent by email from the technical supervisor (TS) on July 8, 2024. Findings: 1. During the first day of the survey on 03/07/2024, the TS confirmed that the AU-480 chemistry analyzer and Access 2 immunoassay endocrinology analyzer were not online yet and therefore no validation and quality control documentation was available for review. 2. The spreadsheet contained patient results for complete blood count (CBC) testing from January-June 2024. 3. The spreadsheet listed all tests that were reported for patients in addition to the CBCs. There were 152 patient specimens tested between 01/15/2024-02/21/2024 that included "AU480" and "Access 2" in the description of the testing that was performed. 4. The testing listed for these 152 patient specimens included the endocrinology analytes prostate specific antigen, thyroid stimulating hormone, thyroxine, triiodothyronine, testosterone, dehydroepiandrosterone sulfate, estradiol, folate, and follicle stimulating hormone, which, according to the TS, were not able to be tested by the laboratory at that time. 5. Requests were made via email on August 6, 7, 8, and 20, 2024 for confirmation of whether the testing was performed at the laboratory, what analyzers were used for the testing, and copies of patient reports to verify if results from these analytes were reported, or whether the specimens were sent to a reference laboratory for testing The laboratory did not respond to the request for records to verify the source of testing.

D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on interview and record review, the laboratory director failed to ensure that verification procedures used were adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method (see D6086 for findings); failed to ensure an approved corrective action plan was followed when proficiency testing results were found to be unacceptable or unsatisfactory (see D6092 for findings); failed to ensure that the quality control programs were established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur (see D6093 for findings); and failed to ensure that the quality assessment programs were established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occurred (see D6094 for findings). The cumulative effect of these systemic problems resulted in the laboratory's inability to ensure the accuracy and reliability of patient test results.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on record review and interview with the assistant manager (AM), the laboratory director (LD) failed to review and approve the initial validation of the hematology analyzer, ensuring that the verification procedures used were adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. Findings: 1. The laboratory began testing with the Diatron Abacus 5 hematology analyzer on 11/22/2022. 2. Record review showed that the initial instrument validation was signed on 11/03/2022 by testing person #1, and was not reviewed and approved by the LD before the instrument was used for patient testing. 3. This was confirmed by the AM on 05/29/2024 at 11:30 AM.
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and interview with the technical supervisor (TS), the laboratory director (LD) failed to ensure a corrective action plan was established and implemented when PT samples received unacceptable results. Findings: 1. The laboratory was enrolled in PT with the American Proficiency

	Institute (API) in modules for Chemistry - Core, Chemistry - Miscellaneous, Hematology/Coagulation, and Microbiology. 2. The LD failed to ensure a corrective action plan was established and implemented when various analytes received unacceptable scores. Cross-refer to tag D5211 for details. 3. The LD failed to ensure that a corrective action plan was implemented when the analyte low-density lipoprotein (LDL) had unsatisfactory performance in two out of three PT events: a. The laboratory received a score of 20% in the 2023 2nd PT event for LDL. The PT records stated "Upon investigation the reported values were above the API by 1 for all samples. QCs and calibration were within range." b. The laboratory received a score of 60% in the 2024 1st PT event for LDL. The PT records stated "After investigation for the root cause analysis determination was the instrument probe went bad. New probe was installed and linearity was performed which had an R^2 of 0.98." c. There was no documentation that a review of LDL testing was performed to determine whether the failures from the 2023 2nd and 2024 1st PT events were related and required additional corrective actions. 4. During the survey on 03/07/2024 at 2:35 PM, the TS confirmed that corrective actions from failed PT scores were not consistently implemented and that the laboratory had two failed scores for LDL in three PT events.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on record review, email communication from the laboratory and interview, the laboratory director (LD) did not ensure that chemistry quality control programs were maintained to identify immediate quality control failures and long term monitoring of quality control test results to maintain the quality of laboratory services. Findings: 1. The laboratory director did not make sure that the technical supervisor performed the following quality control activities to identify, investigate, report on and provide corrective actions for quality control failures. See D5441 for additional findings. a) Weekly reviews of Levey-Jennings (L-J) charts as required by the laboratory's written procedures. b) Use of quality control review forms to document quality control reviews, as stated in the laboratory's written procedures. c) Review quality control testing to identify problems with quality control testing. d) Provide the LD with a random selection of quality control records for the LD to review and verify that the technical supervisor performed quality control reviews as required by the laboratory's written procedures. e) Ensure that quality control reagents and the test system provided numeric results for statistical review for quantitative testing. f) Maintain quality control records, including L-J charts used by the technical supervisor in their reviews to assess the laboratory's quality of services.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:
I. Based on review of the "Quality Assessment Policy", "Clinical Laboratory Quality Assessment Plan", laboratory records, and interview with the assistant manager (AM) and technical supervisor (TS), the laboratory director (LD) failed to ensure that the quality assessment (QA) policies and procedures were followed. Findings: 1. The section labeled "Complaints or Concerns" found in the "Quality Assessment Policy" procedure refers to the documentation of complaints in the "Complaint Log." When interviewed, the AM stated that the complaints were supposed to be entered into a log in the computer system, but the AM did not have access to this log since the laboratory manager had left the practice. The AM confirmed that some complaints could be found in email chains between the AM, TS, and LD. At the time of the survey on 05/29/2024 at 11:00 am, the AM confirmed that the documentation of complaints was not available in an organized fashion showing the complaint, investigation, and remedial actions implemented. 2. The section labeled "Quality Assessment Review" found in the "Clinical Quality Assessment Plan" procedure states: "The Laboratory Director will review quality assessment records from the previous month and discuss fin[d]ings with the staff. The finding will focus on any nonconforming events that may have occurred previously. Staff will help to analyze and resolve the analytical problems. A sampling of patient test records/quality control records will be retrieved and checked for: Accuracy of laboratory-supplied information; Accuracy of medication supplied information; Review of Quality Control Data for the time period; Pre-Analytical, Analytical and Post analytical monitors." During the survey on 05/30/2024 at 11:30 am, the TS stated that these reviews were supposed to have been performed, but there was no documentation showing the results of the monthly data reviews listed above from December 2023 until May 2024. 3. The section labeled "Lab Director/Staff" found in the "Clinical Quality Assessment Plan" procedure states: "Responsibilities of these individuals will ensure that overall quality assurance of their sections include the followings: Reviewing data and identifying problems; Recommending corrective action; Prioritizing identified areas of concern; Implementing a monitoring plan; Implementing alternative corrective action if the solution identified for problems is ineffective...Reviewing QC; Reviewing any safety issues." The procedure failed to identify the titles of the staff who are responsible for implementing the QA activities listed above. 4. During the survey on 03/07/2024 the following problems were written up and filed in the QA monitoring book: a. QA Monitor Report- Pre -analytical, dated 08/11/2022. This was documented as a "Specimen Collection/Submission. Wrong panel accepted" was written in the space provided. The investigation did not include follow up with the person who ordered the wrong testing panel. b. QA Monitor Report- Pre-analytical, dated 03/05/2024. "Detailed Description of Activity: Rejection and Pending log printed for review of errors and samples volume to be completed. Trending or rejection tracked for workflow improvement." The investigation failed to provide the findings of the review of the logs printed. c. QA Monitor Report- Analytical, dated 08/17/2022. This was documented as a specimen missing from the elution plate. The investigation failed to determine why the specimen was missing and were any of the other patients affected by the missing specimen. d. QA Monitor Report- Post-analytical, dated 01/28/2024. The investigation indicated that a specimen was mislabeled and "There is most likely a patient from that day missing a report." The investigation indicated that the last name had been changed. The investigation failed to identify the missing patient report. e. QA Monitor Report- Post-analytical, dated 02/19/2024. The provider inquired about elevated cholesterol and LDL results. The investigation stated that the previous results for the patient had an abnormal high cholesterol and LDL and the results were checked and found to be accurate. The investigation failed to indicate that the provider had been notified of the findings of

	the investigation. The investigation failed to indicate that the test was repeated and verified and/or that the current results were only compared to the previous results. The findings for this post-analytical investigation indicated that there was "No Explanation after investigation." f. QA Monitor Report- Post-analytical, dated 02/20/2024. A provider called with concerns about a patient's calcium level. "Detailed Description of Activity" states "-calcium 11.1 (prior calcium normal) hematocrit was 24 and the hemoglobin was 14 (this makes no sense - either the hematocrit should be higher or the hemoglobin lower)." The laboratory's investigation states "blood sample is much lighter than a patient with a normal RBC count. I found nothing incorrect with her results her levels point to anemia." The investigation failed to indicate that the provider had been notified that the results were acceptable. The findings for this post-analytical investigation indicated that there was "No Explanation after investigation." g. QA Monitor Report-Post-analytical, dated 02/21/2024. "Detailed Description of Activity: On patient X his calcium was 11 please repeat that calcium level either internally or send it to labcorps for confirmation. Going forward, please automatically repeat calcium levels that are more than 10.5" The investigation failed to indicate whether the specimen was repeated and found to be acceptable and that the specimen was sent to labcorp for analysis. The investigation failed to indicate that the testing personnel were notified of the fact that any calcium greater than 10.5 should be repeated, that the final report should identify that the specimen was repeated, and that the policy and procedure manuals were updated to include these new instructions. The findings for this post-analytical investigation indicated that there was "No Explanation after investigation." 5. The investigations listed above failed to identify the root cause of the problems and implement corrective actions to help prevent reoccurrence of the problem. 6. The section labeled "QA Monitoring" found in the "Clinical Quality Assessment Plan" procedure states "Each laboratory section has identified indicators to monitor quality of operations." When interviewed on 05/30/2024 at 11:30 am, the TS confirmed that each laboratory section has not identified indicators to monitor as part of their departmental QA plan. 7. The section labeled "Occurrence Management" found in the "Clinical Quality Assessment Plan" procedure states "The laboratory is actively involved in capturing and analyzing information from nonconforming events to identify systematic laboratory problems, both internally and externally. The following methods are used to detect errors: Random review Error detected within the laboratory section by predetermined internal review process (internal); External Detection Error reported by a physician or other customers/individuals outside the laboratory; Each laboratory section is responsible for capturing/developing a system for detecting errors using the above methods. Summary of laboratory occurrences (including trends) will be reviewed and if improvement are recommended communicated to client/staff." When interviewed on 05/30/2024 at 11:30 am, the TS confirmed that each laboratory section has not been capturing and developing systems for detecting errors and improvement that has been communicated to the laboratory staff. 8. There were no records available at the time of the survey showing that the "Performance Improvement" section of the "Clinical Quality Assessment Plan" had been implemented and reviewed by the laboratory director. 9. During the survey on 06 /18/2024 at 3:00 pm, the TS confirmed that the "Quality Assessment Policy" and "Clinical Laboratory Quality Assessment Plan" failed to be implemented to ensure the quality of the laboratory services provided. II. Based on record review and interview, the laboratory director did not take corrective actions when quality control failures occurred and when quality control reagents and test systems did not provide statistically reviewable test results, when quality control testing was not performed with the frequency required by the laboratory's written procedures. See D5441 and D5779 for findings.

D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on record review and interview, the technical supervisor for chemistry and hematology failed to establish a quality control program appropriate for the testing performed, establish the parameters for acceptable levels of analytic performance, and ensure that these levels were maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results (see D6117 for findings); failed to resolve technical problems and ensure that remedial actions were taken whenever test systems deviated from the laboratory's established performance specifications (see D6118 for findings); and failed to ensure that patient test results were not reported until all corrective actions had been taken and the test system was functioning properly (see D6119 for findings). The cumulative effect of these systemic problems resulted in the laboratory's inability to ensure the accuracy and reliability of patient test results.
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results. This STANDARD is not met as evidenced by: Based on record review and interview, the technical supervisor did not establish quality control programs to ensure acceptable levels of analytic performance for the pre analytic and analytic phases of testing. See D5441 for findings.
D6118	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(5) The technical supervisor is responsible for resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications. This STANDARD is not met as evidenced by: Based on record review and interview, the technical supervisor did not ensure that remedial actions were taken when laboratory test systems did not meet the laboratory's criteria for acceptability. See D5779 for findings.
D6119	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(6)

	The technical supervisor is responsible for ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly. This STANDARD is not met as evidenced by: Based on record review and interview, the technical supervisor did not ensure that patient test results were not reported until all corrective actions were taken and test systems were functioning properly. See D5779 for findings.